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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,440	07/30/2001	Jing Wu	002010-586	2003

21839 7590 12/20/2002

BURNS DOANE SWECKER & MATHIS L L P
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ALEXANDRIA, VA 22313-1404

EXAMINER

KIFLE, BRUCK

ART UNIT PAPER NUMBER

1624


DATE MAILED: 12/20/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/916,440	Applicant(s) Wu et al.
Examiner Bruck Kifle, Ph.D.	Art Unit 1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Oct 7, 2002
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 91-145 is/are pending in the application.
- 4a) Of the above, claim(s) 96-103, 105-108, 123-130, and 132-135 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 91-95, 104, 109-122, 131, and 136-145 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

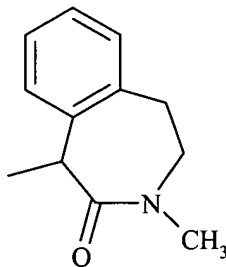
- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9, 9, 10 6) Other:

Art Unit: 1624

Applicant's amendments and remarks filed 10/7/02 have been received and reviewed.

Claims 91-145 are pending in this application.

Applicants are advised that only the elected subject matter is under consideration. That is, compounds and pharmaceutical compositions, wherein W, together with $-C(H)_pC(=X)$, and Q form the ring system



is under consideration.

Claims 96-103, 105-108, 123-130 and 132-135 along with subject matter not embraced by this ring system of the remaining claims are withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter. Election was made without traverse in Paper No. 6.

Applicants are advised that this application still contains non-elected subject matter in the claims. Note, the court in *In re Herrick et al* and *In re Joyce* (both at 115 USPQ 412) held that an election of species requirement was, in fact, a restriction requirement.

Improper Markush Rejection

Claims 91-95, 104, 109-122, 131 and 136-145 are again rejected as being drawn to an improper Markush group, that is, the claims lack unity of invention. The basis of this rejection is

Art Unit: 1624

the same as given in the previous office action and is incorporated herein fully by reference. Applicants argue that the Examiner did not consider the compound as a whole. However, the compounds were in fact considered as whole and determined that their inclusion in a common group is repugnant to principles of scientific classification. In re Harnish restricted the applicant to one core, and indicated in footnote 7, thereof, that a restriction and rejection based on a reference for one ring not being a reference for another was authorized (206 USPQ 300 at 305 and 306). Footnote 7 of Harnish says "having recognized the possibility of rejecting a Markush group on the basis of independent and distinct inventions" in that a reference for one would not be a reference for the other.

Limiting the claims to compounds wherein W, together with $-C(H)_pC(=X)$, and Q form the elected ring system (the benzoazepinone ring) would overcome this rejection.

Claim 145 has 68 pages of compounds, about 800 species. This number of compounds cannot be considered "a reasonable number" according to rule 1.140(a). MPEP rule 1.141(a) is again reproduced below.

§ 1.141 Different inventions in one national application.

(a) Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (1.75) or otherwise include all the limitations of the generic claim.

Art Unit: 1624

Applicants argue that the instant application contains one invention. However, this is not persuasive. First, there was an election of species requirement where Applicants were required to elect a single disclosed species because the claims are drawn to patentably distinct species. Applicants were also advised that should they traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Applicants elected a species without traverse.

Secondly, the number of species claimed in claim 145 is not reasonable. Applicants paid, at most, \$80 for this claim. The cost to search each species is \$45 on the CAS database. Each species has to be searched separately. In re Fressola, 22 USPQ 2nd 1828, indicates that the Examiner may reject for Applicants failure to follow a Rule. Claim 145 is an aggravated example of ultimate species listed in a claim as to avoid fees. The claim is not a Markush claim.

Claim 145 is rejected as failing to comply with 37 CFR 1.141(a).

Applicants are again requested to read the rule and write the claim in dependent form where there is a generic claim present that embraces all of the species in the claim and limit the number of species to a reasonable number of species per claim.

Art Unit: 1624

Provisos

There are provisos in the claims that exclude compounds embraced by the claims. If these provisos are present to avoid prior art, applicants are urgently requested to point out these references to the examiner because of their importance in the examination of the claims. Applicants did not respond to this query.

The search revealed that the elected compound is disclosed in several of Applicants pending applications. See for example WO 99/67221 and WO 98/28268. Also, WO 2001/034571 overlaps generically. Applicants are required to maintain a clear line of demarcation between the applications. See MPEP § 822. Applicants have not indicated what the differences are.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

Art Unit: 1624

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

December 18, 2002



Bruck Kifle
Primary Examiner
Art Unit 1624